DATCP Docket No. 13-R-07
Rules Clearinghouse No. ___

Proposed Hearing Draft
December 19, 2013

PROPOSED ORDER OF THE WISCONSIN DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION ADOPTING RULES

The Wisconsin department of agriculture, trade and consumer protection hereby proposes the following rule ***to amend*** ATCP 55.07(6) and (7)(f) and ***to create*** ATCP 55.07(6) (Note); ***relating to*** drug residues in animals for human food, and affecting small business.

Analysis Prepared by the Department of Agriculture, Trade and Consumer Protection

The Department of Agriculture, Trade and Consumer Protection (DATCP) proposes a rule revision for ch. ATCP 55, Wis. Adm. Code, specifying corrective actions that must be imposed by state-licensed meat establishments on certain livestock producers before the establishment operator accepts animals from the producer for slaughter. The required corrective actions apply to livestock producers who, on two or more occasions during the past year, submit animals testing positive for any illegal drug residue to be slaughtered at a state or federally inspected meat establishment.

Statutes Interpreted

Statute Interpreted: s. 97.42, Stats.

Statutory Authority

Statutory Authority: ss. 93.07 (1), 97.09 (4), and 97.42 (4)Stats.

Explanation of Statutory Authority

DATCP has broad general authority, under s. 93.07 (1), Stats., to adopt rules to implement programs under its jurisdiction. DATCP also has general authority under s. 97.09 (4), Stats., to adopt rules specifying standards to protect the public from the sale of adulterated or misbranded foods. The department has specific authority to promulgate rules related to compulsory inspection of animals, poultry and carcasses under s. 97.42 (4), Stats., which allows the department to establish rules related to the inspections before and after slaughter of all animals and poultry killed or dressed for human consumption at any establishment.

Related Statutes and Rules

Wisconsin's state meat and poultry inspection program is governed by ch. 97, Stats. (Food Regulation), including s. 97.42, Stats. (Compulsory inspection of animals, poultry and carcasses). Chapter ATCP 55 interprets and implements ch. 97, Stats., as it relates to Meat and Meat Food Products.

State meat and poultry inspection programs operate under a cooperative agreement with the USDA's Food Safety and Inspection Service (FSIS) to provide inspection services to small and very small meat establishments. State meat and poultry inspection programs were established by the Wholesome Meat Act of 1967 and the Wholesome Poultry Products Act of 1968, which amended the Federal Meat Inspection Act (FMIA) to create 21 USC 661 and the Poultry Products Inspection Act (PPIA) to create 21 USC 454. Section 11015 of Title XI of the Food, Conservation, and Energy Act of 2008 (the 2008 "Farm Bill"), enacted on June 18, 2008, amended FMIA and PPIA to establish a new voluntary program that will allow certain selected state-inspected meat establishments to sell their products in interstate commerce.

Title 9, Animal and Animal Products, of the Code of Federal Regulations (CFR) interprets and implements the federal FMIA and PPIA. Section 97.42 (4m), Stats., and ch. ATCP 55 adopt certain relevant sections of Title 9 that establish slaughter and processing standards for meat and meat products.

Plain Language Analysis

Medications are important for maintaining healthy livestock. However, if not carefully managed, drug residues may remain in animals submitted for slaughter. Residues of medications, particularly antibiotics and anti-inflammatory agents, in meat can pose a direct health risk to people who consume the meat. For example, some people may have an allergic reaction if exposed to penicillin. The anti-inflammatory drug flunixin may cause gastrointestinal and kidney problems. Drug residues may disrupt normal meat fermentation processes, such as is needed to make summer sausage, and increase the risk that disease-causing bacteria will grow during processing.

Meat establishment operators are expected by the United States Department of Agriculture - Food Safety and Inspection Service (USDA-FSIS) to check the published Residue Repeat Violators list. The list identifies livestock producers whose animals have had two or more positive drug residue test results in the past year. Meat establishment operators are also expected to take appropriate measures before accepting animals from these producers. Recent federal data suggest that dairy cattle are responsible for a high proportion of repeat tissue drug residue offenses. As a leading producer of dairy cattle, the reputation of Wisconsin's agriculture industry is jeopardized by the few Wisconsin producers who repeatedly violate prohibitions against drug residues in livestock and meat products.

Currently ATCP 55 (Meat and meat food products) addresses the production of meat and meat food products starting with the submission of an animal for slaughter for human consumption

and, by reference, adopts United States Department of Agriculture regulations prohibiting the slaughter of "downer" cattle (non-ambulatory) for human food or feed destined for bovine animals.

Current rules prohibit slaughter of a food animal for human consumption or submission of a food animal for slaughter if the person knows or has reason to know the animal is diseased or injured. The proposed rule will further prohibit someone from slaughtering or submitting for slaughter a food animal for human consumption if they know that the animal is adulterated. The rule then defines animals from producers included on the USDA Residue Repeat Violator List for use by Livestock Markets and Establishments as adulterated unless the producer provides written evidence that they have completed a course on proper administration of animal medications. The department will approve an acceptable course or courses. Completion of the approved course(s) will require the involvement of the livestock producer's veterinarian.

The proposed rule also revises ATCP 55.07, which requires a person who knows or has reason to know that he or she is submitting a diseased or injured animal for slaughter to sign and deliver a written statement to the person who will perform the slaughter. The proposed rule will revise the requirement that the written statement include a list of all drugs administered to the animal as treatments or feed within 30 days prior to the slaughter submission date. The rule will instead require that the statement certify that the withdrawal time following administration of all drugs as treatments or feed additives has complied with the manufacturer's recommendations. This revision acknowledges that some drugs may require a longer withdrawal time than 30 days.

Summary of, and Comparison with Existing or Proposed Federal Statutes and Regulations

Federal meat and poultry inspection regulations require meat and poultry processors to adopt Hazard Analysis and Critical Control Point (HACCP) systems. HACCP is an approach for preventing food safety hazards that involves identifying key food processing steps essential for ensuring safety. Plants must develop a plan to monitor and document that each of these key steps is functioning properly and minimizing the risk associated with food safety hazards. As part of their HACCP plan, federally-inspected plants are required by 9 CFR 417.2 (a) (3) (v) to identify preventive measures for food safety hazards that could arise from drug residues. Drug residues include veterinary drugs, pesticides, and environmental contaminants.

One approach for minimizing drug residue risks is for abattoir operators to avoid accepting animals from sources that have had drug residue violations in the past. Since past performance is often the best indicator as to whether an animal may have a drug residue problem, federal plants are expected to consult the federal Residue Repeat Violator List for use by Livestock Markets and Establishments before purchasing animals for slaughter. The National Residue Program (NRP) at FSIS has collected data on drug residues in meat, poultry and egg products since 1967. Producers who are found to have had more than one residue violation in the previous 12 months under this sampling program are placed on the federal Residue Repeat Violator List.

State meat inspection programs operate under a cooperative agreement with the United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS). Under this

agreement, state meat inspection programs are required to adopt regulations that are "at least equal to" federal meat and poultry inspection regulations. In addition, Wisconsin is one of three states recently accepted into the Cooperative Interstate Shipment (CIS) program allowing certain selected meat establishments to ship their products in interstate commerce. States in the CIS program must adopt regulations that are the "same as" federal meat inspection regulations.

The proposed rule will ensure Wisconsin's state meat inspection program is consistent with federal regulations and expectations for minimizing the risk of drug residue violations at state-inspected meat plants. It will enhance the effectiveness of these procedures by adding an additional educational corrective action that would be required of the producer by the abattoir operator well before federal regulatory action is needed.

Comparison with Rules in Adjacent States

Michigan currently does not operate a state meat and poultry inspection program and all meat slaughtered and processed in Michigan is federally-inspected by USDA. Illinois' state meat inspection program includes USDA's Federal-State Cooperative program (formerly known as the "Talmadge-Aiken" program). Under this program, state inspectors conduct federal inspections. Minnesota and Iowa operate state meat inspection programs. All meat and meat products, whether inspected under state meat-inspection programs or by the USDA, are expected to minimize the risk associated with drug residues and plants are expected to consult the USDA's Residue Repeat Violator List for use by Livestock Markets and Establishments before purchasing animals for slaughter. The approach proposed in this rule revision is innovative and goes beyond requirements in neighboring states which operate state meat inspection programs. Although enforcement of the provisions in the proposed rule is expected to be infrequent, the provisions are necessary to protect consumer trust in meat from Wisconsin-inspected establishments.

Summary of Factual Data and Analytical Methodologies

Proposed rule changes were developed after careful analysis of federal regulations and expectations for minimizing the risk of drug residue violations at state-inspected meat plants. The department consulted with a large livestock medication and veterinary services company, and with the Wisconsin Veterinary Medical Association before developing the proposed rule. Both entities supported the intent of the proposed rule.

Effect on Small Business

This rule change is anticipated to have a very slight impact on meat establishment operators, who will be required to determine whether livestock producers presenting animals for slaughter are on the USDA Residue Repeat Violators List. Since very few livestock producers from Wisconsin and neighboring states are on this list, the proposed rule change will have no impact on the vast majority of livestock producers who follow existing regulations and have a strong working relationship with their veterinarian. There will be a minor short-term negative economic impact on livestock producers who must attend a workshop and improve documentation of animal medications as a result of the proposed rule. To the extent that the proposed rule prevents drug

residue problems and condemnation of carcasses, there will be a positive long-term economic impact. The rule will not modify fees or have an economic impact on local governmental units or public utility taxpayers.

DATCP Contact

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Where and When Comments May Be Submitted

Questions and comments related to this this rule may be directed to:

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Rule comments will be accepted up to two weeks after the last public hearing is held on this rule. Hearing dates will be scheduled after this rule is approved by the Board of Agriculture, Trade and Consumer Protection.

SECTION 1. ATCP 55.07 (6) is amended to read:

ATCP 55.07 (6) DISEASED, ~~OR~~ INJURED, OR ADULTERATED ANIMALS; GENERAL. No person may slaughter a food animal for human consumption, or submit a food animal for slaughter for human consumption, if the person knows or has reason to know that the animal is diseased, ~~or~~ injured, or adulterated. Animals, from producers listed in the USDA Residue Repeat Violator List for use by Livestock Markets and Establishments, are considered adulterated unless the producer provides written evidence of completing, in collaboration with a licensed veterinarian, a

course on proper administration of animal medications, approved by the department. This does not prohibit any of the following:

(a) A slaughter that is subject to ante mortem and post mortem inspection by the department or the United States department of agriculture.

(b) The custom slaughter of an animal injured within 24 hours prior to slaughter, provided the animal is not diseased.

(c) The custom slaughter of an animal injured more than 24 hours prior to slaughter if all the following apply:

1. The animal is not diseased.

2. A licensed practicing veterinarian performs an ante mortem and post mortem inspection on the slaughtered animal.

SECTION 2. ATCP 55.07(6)(Note) is created to read:

Note: The USDA Residue Repeat Violator list may be accessed at the following website: http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry and selecting the link to the USDA Residue Repeat Violator List for Use by Livestock Markets and Establishments.

SECTION 3. ATCP 55.07(7) (f) is amended to read:

ATCP 55.07(7) (f) ~~All drugs administered to the animal as treatments or feed additives within 30 days prior to the slaughter submission date, and the last date each drug was administered~~ The withdrawal time following administration of all drugs as treatments or feed additives has complied with manufacturer's recommendations.

SECTION 4. **EFFECTIVE DATE AND INITIAL APPLICABILITY.** This rule takes effect on the first day of the month following publication in the Wisconsin administrative register, as provided under s. 227.22(2)(intro.).

Dated this _____day of _____, 2014.

WISCONSIN DEPARTMENT OF AGRICULTURE,
TRADE AND CONSUMER PROTECTION

By _____
Ben Brancel, Secretary